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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,949	04/13/2004	Rong-Kun Chang	063089-0129	3599

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,949	CHANG, RONG-KUN	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *8-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of power of attorney filed 9/27/07 and response to restriction requirement filed 10/11/07. Claims 1-15 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-7, 14 and 15 in the reply filed on 10/11/07 is acknowledged. Claims 8-13 are thus withdrawn form consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5-7 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al. (US 6,004,582).

Faour discloses a multi-layered delivery device (abstract), that is "useable in different environments for use of the osmotic device include biological environments such as the oral, ocular, nasal, vaginal, glands, gastrointestinal tract, rectum, cervical, intrauterine, arterial, venous, otic, sublingual, dermal, epidermal, subdermal, implant, buccal, bioadhesive, mucosal and other similar environments. Likewise, it may be used in aquariums, industrial warehouses, laboratory facilities, hospitals, chemical reactions and other facilities" (column 4, lines 34-42). The dosage form is in the form of a tablet, pill, sphere, bar, plate or granule (column 6, line 7). The core of the tablet can comprise a number of agents such as osmagents, buffering agents, antioxidants, acacia, alginic acid, polyvinylpyrrolidone, methylcellulose, polyethylene glycol and

many more that used with active agents in tablet formulation (column 9, line 28, 38-65; column 10, lines 14-57) and these materials used in the core or matrix of tablets meet the polymer requirements of claim 2. The multi-layered nature of the dosage form meets claim 3. Claims 5 and 6 describe the properties of the dosage form. The process of preparation of the dosage form is exemplified in at least Examples 1-4 and method claim 14 read on Faour's method. Faour formulates a number of active agents as multilayered tablets (column 13, line 38 to column 16, line 44) and included in this list is riboflavin (column 16, line 31) with the teaching of the riboflavin meeting claim 7.

4. Claims 1, 2, 4-7, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (US 6,197,331).

Lerner discloses controlled release solid composition for the oral cavity or pharmaceutical oral patch (abstract) with the disc of claims 14 and 15 reading on the patch; the composition contains adhesive and release layer (column 8, lines 20-25) meeting the requirement for as layered dosage form in which one surface is adhesive, thus meeting claim 4 and another surface, non-adhesive (column 7, lines 53 and 54); polymer in the adhesive layer is EUDRAGIT type polymer (column 11, lines 24 and 25; column 7, lines 25-28, 45-50); the matrix can also contain plasticizers such as polyethylene glycol, castor oil (column 11, line 66 to column 12, line 5) with the polymer or the oil meeting claim 2. Lerner specifically teaches that "any agent can be used, depending on the purpose of therapy" (column 15, lines 12 and 13) and proceeds to name specific ones and cyclosporin is mentioned as a peptide or protein drug (column 16, lines 52-56) meeting claim 7. The mixing of the polymer with the active agent and eventually

formulating the composition into patch (column 17, lines 26-34) meets the requirements of the method claims 14 and 15. Lerner thus teaches all the limitations of the designated claims.

5. Claims 1, 2, 5-7 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Christenson et al. (US 3,065,143, provided by applicant on form PTO 1449).

Christenson discloses a tablet formulation containing doxylamine and hydrophilic polymer (column 1, lines 13, 14, 55-70; column 2, lines 19, 20; columns 7 and 8) and doxylamine is mentioned in example 6. Christenson teaches the limitations of the designated claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
Patent Examiner
Tech. Center 1600